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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,688	10/25/2001	Theodore R. Sana	10010819-1	3172

7590 02/24/2005
AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001,688

Applicant(s)

SANA ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

The applicant's response filed 12/09/04 to the Office action has been entered. Claims 6-8 and 15-24 are pending.

1. Claims 6-8 and 15-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 6-8 and 15-23 are vague and indefinite because it is unclear what is the size of the oligonucleotide probe. Since the specification states that the oligonucleotide generally refers to a nucleotide multimer of about 10-100 nucleotides in length (See pg. 4, lines 28-32), it is unclear what is the size of the oligonucleotide probe. Clarification is required.

The response argues that the term "oligonucleotide" is commonly used term in the patents and literatures. This is true. However, there is no definition in terms of the term "oligonucleotide probe" in the specification. Thus, the rejection is maintained.

2. Claims 6-8, 15-18 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner (5,604,097, issued February 18, 1997) in view of Oliva et al, (BioTechniques, 2001, Vol. 31(1) pg. 74-76 and 78-81).

Brenner discloses a method of tracking, identifying and sorting classes of molecules by the use of oligonucleotide tags. The tag is immobilized on the solid support, which comprises a wide variety of composition including glass (See column 12, lines 40-47). The solid support may comprise micro particles or arrays where uniform population of tag complements is synthesized (See column 13, lines 7-9 and column 35, lines 1-18). The oligonucleotide tag is covalently or

non-covalently linked to the surfaces of the microparticle supports (See column 13, lines 52-58).

The oligonucleotide tag is from 12 to 60 nucleotides in length (See column 9, line 14-15).

Brenner does not disclose that the hybridization is performed in the presence of urea with the concentration, 4M at about 50⁰ C.

Oliva et al. disclose *in situ* hybridization with urea hybridization buffer (See pg. 74, Protocol 1). The incubation reaction is over night at 50⁰ C (See pg. 74, Protocol 1). The urea concentration used is 1.0, 2.0 and 4.0 M. (See pg. 78, Table 1).

One of ordinary skill in the art would have been motivated to modify the method of Brenner by applying urea hybridization buffer in the method for specific hybridization. Oliva et al. indicate that the hybridization buffer containing urea decreases the annealing temperature and the specificity of the hybridization is retained (See pg. 79, column 2, second paragraph). Thus, it would have been prima facie obvious to apply the hybridization buffer containing urea of Oliva et al. to make specific hybridization on the array of Brenner.

The response argues that the teachings of Brenner is mischaracterized and the Office action has no point that Brenner disclose an array of oligonucleotide tags, and any oligonucleotide tag is covalently linked to a solid support and the Office refers to solid supports linked to tag complements and not solid supports linked to the oligonucleotide tags themselves. The tag complements of Brenner are referred to oligonucleotide tag, which is immobilized onto solid phase supports (See the Abstract). The teachings of Brenner also indicate that the complement of the tag sequence is linked to their surface covalently or non-covalently (See column 13, lines 52-56). The supports comprise particles or arrays (See column 13, lines 5-7).

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Thus the teachings of Brenner et al. do suggest that there is an array on which the oligonucleotide tags are linked.

The response further argues that Brenner warns the reagents used in the hybridization assay that alter the stability of nucleic acid duplexes (of which urea would be an example) because that can be incompatible with further manipulations. However, Brenner does not specifically disclose any reagent, which alters the stability of nucleic acid duplexes and can be incompatible with further manipulations at all. Moreover, Brenner does not specifically teach what kind of manipulation is. Therefore, based upon the positive teachings of Oliva et al. as set forth below, by using urea in hybridization buffer, the annealing temperature is reduced and the specificity of the hybridization is retained (See pg. 79, column 2, second paragraph).

The response also argues that Brenner disclose DNA/DNA hybridization methods using oligonucleotide array and Oliva et al. disclose *in situ* RNA/RNA hybridization methods and none of the cited references suggest what is being claimed. However, Oliva et al. suggest that the nucleic acid duplex destabilizing molecule, urea lowered annealing temperature, while the specificity of the hybridization was retained (See pg. 79, column 2, second paragraph). The suggestions of Oliva et al. apply to nucleic acid molecule, which includes DNA and RNA.

Finally, the Applicants submit that the claimed method provides unexpected results. As suggested by Oliva et al. above, the hybridization buffer containing urea in which a lowered annealing temperature was ensured and the specificity of hybridization was retained. Thus, the claimed invention is not presented as an unexpected result.

Based upon the analysis above, the rejection is maintained.

Summary

3. No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

4. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

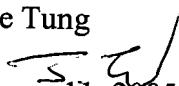
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

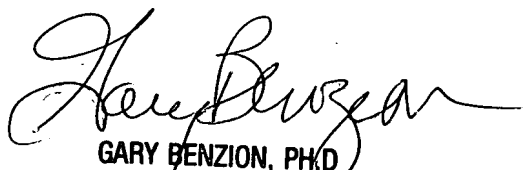
Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

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5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung


February 11, 2005


GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600